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October 13, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: Docket #99D-3082: International Conference of Harmonization; Choice of Control Group in Clinical Trials

To Whom it May Concern:

I have recently reviewed your notice regarding the above mentioned document. I have several concerns about this document. As a surgeon that is attempting to modify the way that surgical trials are performed, in favor of increased of safety for patients both in the trial phase as well as clinical phase of therapeutic development, the proposed docket is inadequate from several perspectives. It provides no guidance whatsoever on the assessment of risk versus benefit in a trial design, nor does it give guidance on the reasonableness of a decision regarding this matter. This is, of course, critical in particular in surgical trials where risk-related issues, if anything, are magnified. It gives no guidance as to who will make such decisions.

It does not begin to go far enough to address the issue of who benefits from a clinical trial: the subject in the current trial, a subject in (for example) a cross-over arm, patients with a similar disease, or society in general. As far as I can tell, the most that a patient can be asked to consent to is the experience of discomfort as well as a delay in therapy, and in the latter case only if it is deemed acceptable. Many studies involve more than minimal risk, and these guidelines would make it nearly impossible to design an effective trial of many invasive therapies.

In summary, I find nothing in these guidelines to provide adequate protection of subjects from the current method of relatively uncontrolled development of surgical and invasive therapies. I maintain that the voluntary participation of a small number of subjects in a study with defined and reasonable risks is far more ethical than the involuntary exposure of hundreds or thousands of unknowing patients to an operation of unknown risks and unproven benefits. I am afraid that this current document does not begin to provide adequate protection for patients that are offered unproven surgical and invasive therapies.

99D-3082 C 1

Sincerely yours,

Thomas Freeman MD

Thomas B. Freeman, M.D., F.A.C.S.
Professor
Department of Neurosurgery

TBF:fm

Dictated, but not read by.

CC: Robert Temple
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